



Q & A: Fraud and Abuse Related to 2009 H1N1 Influenza Vaccine

January 15, 2010

**Purpose and
Target
Audience:**

The purpose of this document is to provide information to state/local immunization programs regarding options for reporting certain criminal, fraud and abuse matters relating to the 2009 H1N1 influenza vaccine and ancillary supplies.

Background:

The Centers for Disease Control and Prevention (CDC) continues to receive reports regarding charges, distribution and marketing irregularities involving the 2009 H1N1 influenza vaccine and ancillary supplies. CDC reviews any information provided and uses its best efforts to forward such reports to appropriate federal (and in some cases, state) regulatory and other agencies for their awareness and possible action.

Q 1: What types of fraud and abuse may arise with respect to the 2009 H1N1 influenza vaccine and ancillary supplies?

A 1:

- Charging for the 2009 H1N1 monovalent influenza vaccine
***Note:** 2009 H1N1 influenza vaccine doses are provided at no cost to providers by the Federal government. Patients may not be charged for the vaccine or ancillary supplies. However, administration fees may be charged.*
- Requesting an out-of-pocket fee directly from the patient that is above the maximum regional Medicare allowable charge. The current Medicare administration reimbursement rates is available online at:
<http://www.cms.hhs.gov/AdultImmunizations/Downloads/09AdminRates.pdf>
- Selling 2009 H1N1 influenza vaccine or ancillary supplies provided by the Federal government
- Counterfeit vaccines
- Adulteration of vaccine
- Theft of vaccine
- Consumer fraud
- Marketing and advertising, often on websites or via the internet, including fraudulent product claims, bogus products, and implied endorsement by federal agencies (including use of federal government agency logos)
- Diversion, which includes situations where legitimate prescription drugs/vaccines are:
 1. Entered into illegal channels (i.e., black market, illegal Internet sales, sales without prescription, etc.) and/or
 2. Acquired or obtained by an illegal method (cargo/wholesale/manufacturer/ distributor theft, smuggling into the USA, illegal sale to unauthorized party without prescription, etc.).



Q 2: What options exist for reporting suspected fraud and abuse issues related to 2009 H1N1 influenza vaccine and ancillary supplies?

A 2: State and local partners should follow any routine procedures they may have in place for notifying appropriate authorities of any suspected fraud or abuse matters. For example, allegations of charging for doses, or sales, of 2009 H1N1 vaccine should be directly reported to their State Attorney General's Office. Any suspected criminal activity should be reported to appropriate state and local authorities, as well as to the Food & Drug Administration - Office of Criminal Investigations.

Below is a list of federal enforcement agencies, along with the criminal, fraud and abuse matters which fall under their purview. State and local partners may directly report criminal activity, fraud and abuse matters to relevant agencies.

1) Food and Drug Administration (FDA), Office of Criminal Investigations:

- Scams or schemes involving efforts to market bogus vaccine or flu treatments;
- Any potentially illegal vaccine-related activity such as theft, diversion, adulteration (misbranding), potential counterfeits, etc;
- Marketing of fraudulent or bogus 2009 H1N1 products claiming to prevent or treat 2009 H1N1 influenza;
- Implied endorsement of any 2009 H1N1 product by HHS/FDA and/or improper use of HHS/FDA logos on company websites or other marketing materials.

Suspected criminal activity relating to FDA regulated products and the 2009 H1N1 flu virus may be reported directly to FDA-OCI at the following website:

<http://www.fda.gov/OCI>

2) Federal Trade Commission (FTC), Bureau of Consumer Protection:

Scams (especially via the internet or websites) including unsupportable product claims, false advertising, and fraudulent or bogus products, as well as implied endorsement by federal agencies and improper use of federal agency logos on company websites or other marketing materials

Complaints may be submitted directly to the FTC at the following website:

<https://www.ftccomplaintassistant.gov/>

State and local partners may report any such matters which come to their attention directly to the CDC by sending an email to the CDC H1N1 Vaccine Fraud mailbox at H1N1FraudAbuse@cdc.gov. The email should include their contact information as well as a detailed description of the situation including when it occurred. CDC will review the information provided and will use its best efforts to forward these emails to one or more of the agencies listed above, and possibly to others as warranted, for their awareness and possible action.